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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,408	01/08/2002	Robert Amess	2543-1-020	3867

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,408	AMESS ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *January 8, 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-24 are pending in the application and are currently under prosecution.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13:

Group A (consists of 1 invention).

Claims 1, 5, 6(as it is drawn to feature BF-1), 7(as it is drawn to feature BF-1), 8, and claim 13-19 (as they are drawn solely to antibody to BF-1) are drawn to an *in vitro* method, as contemplated in the specification, for immunological screening and/or diagnosis of breast cancer in a human patient comprising assaying one protein feature, BF-1, for differential expression. (It is noted that the first invention named is drawn to diagnosis of breast cancer comprising assaying BF-1) as well as an antibody to BF-1.

Group B (consists of $5.8X10^{120}$ inventions).

Claims 1, 5, 6 (as the features of tables I-IV are drawn to the features claimed in claim 1), 7 (as the features of tables I-IV are drawn to the features claimed in claim 1), 8, are drawn to an *in vitro* method, as contemplated in the specification, for immunological screening and/or diagnosis of breast cancer in a human patient comprising assaying one or more differentially present protein features wherein said protein features are any one or more of the 81 features claimed in claim 1. It is noted that by factorial analysis, the number of methods claimed in Group B is $5.8X10^{120}$, that is $81! = 5.8X10^{120}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein

feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group C (consists of $9.6X10^{161}$ inventions).

Claims 1, 4-8 in, are drawn to an *in vitro* method, as contemplated in the specification, for immunological screening and/or diagnosis of breast cancer in a human patient comprising identifying one or more differentially present protein features wherein said protein features are any one or more of the 81 and 21 features claimed in claims 1 and 4 or 102 features disclosed in tables I-IV. It is noted that tables I-IV in combination recite the 102 features claimed in claims 1 and 4. It is noted that by factorial analysis, the number of combinations claimed in Group C is $9.6X10^{161}$, that is $102! = 59.6X10^{161}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group D (consists of $5.8X10^{120}$ inventions).

Claims 1, 9 (as it is drawn to the protein features of tables I-IV recited in claim 1) are drawn to an *in vitro* method, as contemplated in the specification, for screening and/or diagnosis of breast cancer in a human patient comprising identifying one or more differentially present protein features comprising amplification of nucleic acid coding for one

or more of the protein features defined in tables I-IV, as they are drawn to those recited in claim 1. It is noted that by factorial analysis, the number of methods claimed in Group D is $5.8X10^{120}$, that is 81! = $5.8X10^{120}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group E (consists of $5.8X10^{120}$ inventions).

Claims 1, 10 (as drawn to primary tumor cells), 11-12 are drawn to an *in vivo* method for screening and/or diagnosis of breast cancer in a human patient comprising a whole body or organ scan to determine localization of breast tissue cells. It is noted that by factorial analysis, the number of methods claimed in Group E is $5.8X10^{120}$, that is 81! = $5.8X10^{120}$, or a single method per combination of protein features recited in claim 1. If Applicant were to elect one of these inventions, Applicant is required to elect a single method with a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group F (consists of 101 inventions).

Claims 13-16, 17 (as it is drawn to antibodies), 18, 19 are drawn to 101 antibodies (those other than that to BF-1), each one of which that

specifically binds to one of the 102 protein features disclosed in tables I-IV.

Group G (consists of 102 inventions).

Claims 17 (as it is drawn to nucleic acid probes), 20, 21 are drawn to 102 sets of probes, each one of which that specifically hybridizes to one of the 102 polynucleotides encoding the 102 protein features disclosed in tables I-IV.

Group H (consists of $5.8X10^{120}$ inventions).

Claim 2 is drawn to an *in vitro* method, as contemplated in the specification, for monitoring and/or assessing beast cancer treatment in a human subject comprising assaying one or more differentially present protein features wherein said protein features are any one or more of the 81 features claimed in claim 2. It is noted that by factorial analysis, the number of methods claimed in Group H is $5.8X10^{120}$, that is $81! = 5.8X10^{120}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group I (consists of $9.6X10^{161}$ inventions).

Claims 2 and 4 are drawn to an *in vitro* method, as contemplated in the specification, for monitoring and/or assessing breast cancer treatment in a human subject comprising assaying one or more differentially present protein features wherein said protein features are any one or more of the 81 and 21 features claimed in claims 2 and 4. It

is noted that by factorial analysis, the number of combinations claimed in Group I is $9.6X10^{161}$, that is $102! = 59.6X10^{161}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group J (consists of $5.8X10^{120}$ inventions).

Claim 2 is drawn to an *in vitro* method, as contemplated in the specification, for monitoring and/or assessing breast cancer treatment in a human subject comprising identifying one or more differentially present protein features comprising amplification of nucleic acid coding for one or more of the protein features claimed in claim 2. It is noted that by factorial analysis, the number of methods claimed in Group J is $5.8X10^{120}$, that is $81! = 5.8X10^{120}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group K (consists of $5.8X10^{120}$ inventions).

Claim 2 is drawn to an *in vivo* method, as contemplated in the specification, for monitoring and/or assessing breast cancer treatment in a human subject comprising a whole body or organ scan to determine

localization of breast tissue cells. It is noted that by factorial analysis, the number of methods claimed in Group K is $5.8X10^{120}$, that is 81! = $5.8X10^{120}$, or a single method per combination of protein features recited in claim 2. If Applicant were to elect one of these inventions, Applicant is required to elect a single method with a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group L (consists of $5.8X10^{120}$ inventions).

Claim 3 is drawn to an *in vitro* method, as contemplated in the specification, identifying the presence or absence of metastatic breast cancer in a human subject comprising assaying one or more differentially present protein features wherein said protein features are any one or more of the 81 features claimed in claim 3. It is noted that by factorial analysis, the number of methods claimed in Group L is $5.8X10^{120}$, that is 81! = $5.8X10^{120}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group M (consists of $9.6X10^{161}$ inventions).

Claims is 3-4 are drawn to an *in vitro* method, as contemplated in the specification, identifying the presence or absence of metastatic breast

cancer in a human subject comprising assaying one or more differentially present protein features wherein said protein features are any one or more of the 81 and 21 features claimed in claims 3 and 4. It is noted that by factorial analysis, the number of combinations claimed in Group M is $9.6X10^{161}$, that is $102! = 59.6X10^{161}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group N (consists of $5.8X10^{120}$ inventions).

Claim 3 is drawn to an *in vitro* method, as contemplated in the specification, identifying the presence or absence of metastatic breast cancer in a human subject comprising assaying one or more differentially present protein features comprising amplification of nucleic acid coding for one or more of the protein features claimed in claim 3. It is noted that by factorial analysis, the number of methods claimed in Group N is $5.8X10^{120}$, that is $81! = 5.8X10^{120}$, or a single method per combination of protein features. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group O (consists of $5.8X10^{120}$ inventions).

Claim 3 is drawn to an *in vivo* method, as contemplated in the specification, identifying the presence or absence of metastatic breast cancer in a human subject comprising a whole body or organ scan to determine localization of breast tissue cells. It is noted that by factorial analysis, the number of methods claimed in Group O is $5.8X10^{120}$, that is $81! = 5.8X10^{120}$, or a single method per combination of protein features recited comprising a whole body or organ scan to determine localization of breast tissue cells. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific protein feature or specific combination of features for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group P (consists of $9.6X10^{161}$ inventions).

Claims 22-23 are drawn to a method for the treatment of breast cancer comprising administering one or more antibodies against one or more of the protein features defined in Tables I-IV in association with an agent capable of causing cell death. It is noted that by factorial analysis, the number of methods claimed in Group P is $9.6X10^{161}$, that is $102! = 9.6X10^{161}$, or a single method per combination of antibodies to protein features recited. . If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific antibody or specific combination of antibodies for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group Q (consists of $9.6X10^{161}$ inventions).

Claims 22-23 are drawn to a method for the treatment of breast cancer comprising administering one or more antibodies against one or more of the protein features defined in Tables I-IV conjugated with an agent capable of causing cell death. It is noted that by factorial analysis, the number of methods claimed in Group Q is $9.6X10^{161}$, that is 102! = $9.6X10^{161}$, or a single method per combination of antibodies to protein features recited. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific antibody or specific combination of antibodies for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group R (consists of $9.6X10^{161}$ inventions).

Claim 24 is drawn to the use of one or more antibodies against one or more of the protein features defined in tables I—IV in association with an agent capable of causing cell death in the manufacture of a medicament for the treatment of breast. It is noted that by factorial analysis, the number of methods claimed in Group R is $9.6X10^{161}$, that is 102! = $9.6X10^{161}$, or a single method per combination of antibodies to protein features recited. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific antibody or specific combination of antibodies for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

Group S (consists of $9.6X10^{161}$ inventions).

Claim 24 is drawn to the use of one or more antibodies against one or more of the protein features defined in tables I—IV conjugated with an agent capable of causing cell death in the manufacture of a medicament for the treatment of breast. It is noted that by factorial analysis, the number of methods claimed in Group S is $9.6X10^{161}$, that is 102! = $9.6X10^{161}$, or a single method per combination of antibodies to protein features recited. If Applicant were to elect one of these inventions, Applicant is required to elect a single method using a specific antibody or specific combination of antibodies for examination. It is noted for Applicant's convenience that this is not an election of species requirement but rather a requirement to elect a single invention for examination.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

Group A, invention 1, claims 1, 5, 6-in-part, as disclosed above, 7-in-part, as disclosed above, 8, 13-19-in-part, (that is all of13-19-in-part, as disclosed) above form a single general inventive concept.

Group B is drawn to $5.8X10^{120}$ additional methods.

Group C is drawn to $9.6X10^{161}$ additional methods.

Group D is drawn to $5.8X10^{120}$ additional methods.

Group E is drawn to $5.8X10^{120}$ additional methods.

Group F is drawn to 101 additional products.

Group G is drawn to 102 additional products.

Group H is drawn to $5.8X10^{120}$ additional methods.

Group I is drawn to $9.6X10^{161}$ additional methods.

Group J is drawn to $5.8X10^{120}$ additional methods.

Group K is drawn to $5.8X10^{120}$ additional methods.

Group L is drawn to $5.8X10^{120}$ additional methods.

Group M is drawn to $9.6X10^{161}$ additional methods.

Group N is drawn to $5.8X10^{120}$ additional methods.

Group O is drawn to $5.8X10^{120}$ additional methods.

Group P is drawn to $9.6X10^{161}$ additional methods.

Group Q is drawn to $9.6X10^{161}$ additional methods.

Group R is drawn to $9.6X10^{161}$ additional methods.

Group S is drawn to $9.6X10^{161}$ additional methods.

4. Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

5. Groups A-C contain claims directed to more than one species of the generic invention.

Claims 1 and 7 are generic to a plurality of disclosed patentably distinct species comprising immunoassay methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the immunoassays are (a) western blot, (b) ELISA, (c) radio immunoassay, (d) sandwich immunoassay, (e) immunoprecipitation assay, (f) precipitin reaction, (g) gel perfusion precipitin reaction, (h) immunodiffusion assay, (i) agglutination assay, (j) complement-fixation assay, (k) immunoradiometric assay, (l) fluorescent immunoassay, (m) protein A immunoassay, (n) immunoprecipitation assay, (o) immunohistochemical assay, all of claim 8.

6. Applicant is required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as

provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 872-9306.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
September 5, 2004